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APPLICATION NO). 1	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/622,621		07/18/2003	Jan Weber	S63.2-10856-US01	S63.2-10856-US01 2650	
490	7590	09/19/2006		EXAMINER		
•		& STEINKRAUS,	KOHARSKI, CHRISTOPHER			
6109 BLUE CIRCLE DRIVE SUITE 2000				ART UNIT	PAPER NUMBER	
MINNETC	MINNETONKA, MN 55343-9185			3763		
				DATE MAILED: 09/19/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

•			_	6			
		Application No.	Applicant(s)				
Office Action Summary		10/622,621	WEBER ET AL.				
		Examiner	Art Unit				
	•	Christopher D. Koharski	3763				
Period fe	The MAILING DATE of this communication apports Reply	pears on the cover sheet with the	correspondence address				
WHIC - Exte after - If NO - Failt Any	IORTENED STATUTORY PERIOD FOR REPLICHEVER IS LONGER, FROM THE MAILING Densions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Depriod for reply is specified above, the maximum statutory period ure to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be ti will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONI	N. mely filed n the mailing date of this communicat ED (35 U.S.C. § 133).				
Status	•						
1)[🛛	Responsive to communication(s) filed on 18 J	ulv 2003.					
2a)□		s action is non-final.					
3)□	osecution as to the merits	is					
,—	closed in accordance with the practice under l						
Disposit	ion of Claims						
41⊠	Claim(s) 1-63 is/are pending in the application	L.					
1/623	4a) Of the above claim(s) is/are withdra						
. 5)□	Claim(s) is/are allowed.						
	Claim(s) is/are rejected.						
· ·	Claim(s) <u>48-63</u> is/are objected to.		•				
	Claim(s) <u>1-63</u> are subject to restriction and/or	election requirement.					
Applicat	tion Papers						
9)	The specification is objected to by the Examine	er.					
	☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
,	Applicant may not request that any objection to the						
	Replacement drawing sheet(s) including the correct	tion is required if the drawing(s) is o	bjected to. See 37 CFR 1.12	1(d).			
11)	The oath or declaration is objected to by the E	xaminer. Note the attached Office	e Action or form PTO-152	•			
Priority	under 35 U.S.C. § 119						
•	Acknowledgment is made of a claim for foreign ☐ All b)☐ Some * c)☐ None of:		a)-(d) or (f).				
	1. Certified copies of the priority documen						
	2. Certified copies of the priority documen						
	3. Copies of the certified copies of the price		ved in this National Stage				
	application from the International Burea	·					
•	See the attached detailed Office action for a list	t of the certified copies not receive	ea.				
Attachme							
	ice of References Cited (PTO-892) ice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summai Paper No(s)/Mail I					
3) 🔲 Info	rmation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date	5) Notice of Informal 6) Other:					

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DETAILED ACTION

Claim Objections

Claim 48-63 objected to because of the following informalities: Claim 48 is missing and the subsequent claims are then misnumbered due its absence.

Appropriate correction is required.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim1-21, 22-23, 28, 39-45, 46-47 and 49, drawn to process of forming a medical device, classified in class 264, subclass 219.
- II. Claims 25-27, 29, and 30-31, drawn to medical device formed of a polymer, classified in class 428, subclass 35.1.
- III. Claims 53-63, drawn to a mold, classified in class 264, subclass 308.

Inventions II are III related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination of the mold has separate utility such as it can be used to make many different devices and the device can be created by different device such as an extruder. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR

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1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the medical device as claimed can be made using a different process such as extrusion.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 9/12/2006

Christopher D. Koharski AU 3763

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